ESTIMATED ANNUALIZED BURDEN TABLE

Respondents	Number of respondents	Number of responses/respondent	Avg. burden/response (in hrs)	Total burden hours
Office-based physicians:				
Induction Interview	3,350	1	28/60	1,563
Patient Record Form	2,513	30	4/60	5,026
CCSS	712	1	15/60	178
Community Health Center:				
Induction Interview—Directors	104	1	20/60	35
Induction Interview—Providers	312	1	35/60	182
Patient Record Form	312	30	5/60	780
CCSS	312	1	15/60	78
Total				7,842

Dated: January 5, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E6–211 Filed 1–11–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2004P–0406 and 2004P–0407]

Determination That Celestone Soluspan (Betamethasone Sodium Phosphate and Betamethasone Acetate) Injection and Celestone (Betamethasone Sodium Phosphate) Injection Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that two drug products—Celestone Soluspan (betamethasone sodium phosphate and betamethasone acetate) injection and Celestone (betamethasone sodium phosphate) injection—were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for betamethasone sodium phosphate and betamethasone acetate injection and betamethasone sodium phosphate injection if all other legal and regulatory requirements are met. However, in considering whether to file an ANDA for betamethasone sodium phosphate and betamethasone acetate injection, future applicants are advised that Celestone Soluspan injection may not be commercially available because, under a consent decree between FDA and the manufacturer, it is being made available in certain instances of medical necessity only. The reasons for its unavailability are not safety or effectiveness considerations associated with the drug product in general, but specific to the manufacturer. An ANDA applicant who is unable to obtain Celestone Soluspan injection for bioequivalence testing must contact the Office of Generic Drugs for a determination of what is necessary to show bioavailability and same therapeutic effect. If the reference listed drug (RLD) product becomes commercially available prior to ANDA approval, the ANDA applicant will need to show bioequivalence to the RLD product.

FOR FURTHER INFORMATION CONTACT: Carol E. Drew, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

On September 7, 2004, Hikma Farmaceutica (Portugal) LDA submitted two citizen petitions (Docket Nos. 2004P–0406/CP1 and 2004P–0407/CP1) to FDA under 21 CFR 10.30 requesting that the agency determine whether Celestone Soluspan (betamethasone sodium phosphate and betamethasone acetate) injection equivalent to 6 milligrams (mg) base/milliliter (mL) (NDA 14–602) and Celestone (betamethasone sodium phosphate) injection equivalent to 3 mg base/mL (NDA 17–561), both manufactured by Schering-Plough Corp. (Schering), were withdrawn from sale for reasons of safety or effectiveness. Celestone Soluspan injection and Celestone injection are corticosteroids used for their anti-inflammatory effects in disorders of many organ systems. Schering ceased manufacture of Celestone injection in March 2004, and it was moved from the prescription drug product list to the "Discontinued Drug Product List" section of the Orange Book.

Schering has not discontinued manufacture of Celestone Soluspan injection; however, as a result of a May 2002 consent decree addressing manufacturing concerns, Schering's manufacture and distribution of Celestone Soluspan injection has been limited to providing the drug for certain medically necessary uses under a limited distribution program. Celestone Soluspan injection is being distributed as medically necessary for the following uses: (1) Neonatal use (fetal lung maturation), (2) epidural route for the management of pain due to radiculopathy in patients not responsive to systemic drug therapy and other adjunctive therapies, and (3) intra-articular and soft tissue injections for synovitis of osteoarthritis, acute gouty arthritis, nonspecific tenosynovitis, and acute and subacute bursitis. Information regarding the current distribution for Celestone Soluspan injection by Schering can be found on FDA's Drug Shortage Web site: *http://www.fda.gov/cder/drug/shortages/celestone.htm.*

FDA has reviewed its records and, under § 314.161, has determined that Celestone Soluspan (betamethasone sodium phosphate and betamethasone acetate) injection and Celestone (betamethasone sodium phosphate) injection were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list betamethasone sodium phosphate in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to betamethasone sodium phosphate may be approved by the agency. ANDAs that refer to betamethasone sodium phosphate and betamethasone acetate injection also may be approved by the agency; however, FDA recommends that in considering whether to file an ANDA for this drug product, future applicants be advised that the RLD may not be commercially available because it is being made available in certain instances of medical necessity only. An ANDA applicant who is unable to obtain Celestone Soluspan injection for bioequivalence testing must contact the Office of Generic Drugs for a determination of what showing is necessary to satisfy the requirements of section 505(j)(2)(A)(iv) of the act. If an ANDA is approved without a showing of bioequivalence, the approved product will not be granted an AB rating in the Orange Book. Future applicants for betamethasone sodium phosphate and betamethasone acetate injection are advised that if the RLD product becomes commercially available prior to ANDA approval, the ANDA applicant will need to show bioequivalence to the RLD product.

Dated: January 4, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–178 Filed 1–11–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA–225–05–8006]

Memorandum of Understanding Between the United States Food and Drug Administration Department of Health and Human Services and the Australian Pesticides and Veterinary Medicines Authority, Australia

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the United States Food and Drug Administration, Department of Health and Human Services and the Australian Pesticides and Veterinary Medicines Authority (APVMA), Australia. This MOU is intended to establish an information-sharing arrangement between APVMA and FDA. The Participants intend to strengthen the exchange of knowledge and expertise to enhance the efficiency and effectiveness of their respective roles. This MOU focuses on cooperation in relations to the operational aspects of animal drug regulation and is not intended to cover broader government regulatory policy or to cover areas not falling under the common jurisdictional purview of the Participants.

DATES: The agreement became effective October 20, 2005.

FOR FURTHER INFORMATION CONTACT: Matthew E. Eckel, Office of International Programs, Food and Drug Administration, 5600 Fishers Lane (HFG–1), Rockville MD, 20857, 301–827–4480, FAX 301–480–0716.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: January 4, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S